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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,199	09/01/2006	John Brownlie	ERP02.001APC1	6472

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KNOBBE MARTENS OLSON & BEAR LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

EXAMINER
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ARCHIE, NINA

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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02/08/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/563,199	<b>Applicant(s)</b> BROWNLIE ET AL.	
	<b>Examiner</b> Nina A. Archie	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/10/2010</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This Office Action is responsive to Applicant's amendment and response filed 11-10-10. Claims 1, 9, and 19, have been amended. Claims 1 and 8-19 are pending. Claims 16-19 are withdrawn from consideration. Claims 1 and 8-15 are currently under examination.

### **Information Disclosure Statement**

2. The information disclosure statement filed 11/10/2010 has been considered. An initialed copy is enclosed.

### **Objections/Rejections Withdrawn**

3. In view of the Applicant's amendments and remarks the following objections/rejections are withdrawn.

a) Rejection to claims 1, 8-9, 12, and 15 under 35 U.S.C. 103(a) as being unpatentable over (Mackenzie et al EP 0415794A1 Date September 6, 1991), (Hansen et al US Patent No. 5,665,363 Date September 9, 1997), and (Hymas et al US Application No. 20020150593 US Publication Date October 17, 2002) is withdrawn in light of applicant's amendment thereto.

b) Rejection of claims 1, 8-10, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Mackenzie et al EP 0415794A1 Date September 6, 1991), (Hansen et al US Patent No. 5,665,363 Date September 9, 1997), (Hymas et al US Application No. 20020150593 US Publication Date October 17, 2002), and (Acree et al US Patent No. 4,824,785 Date January 28, 1986) is withdrawn in light of applicant's amendment thereto.

g) Rejection of claims 1, 8-9, 11-12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Mackenzie et al EP 0415794A1 Date September 6, 1991), (Hansen et al US Patent No. 5,665,363 Date September 9, 1997), (Hymas et al US Application No. 20020150593 US Publication Date October 17, 2002), and (Brown et al US Patent No. 5,661,006 Date August 26, 1997) is withdrawn in light of applicant's amendment thereto.

h) Rejection of claims 1 and 8-15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement ) is withdrawn in light of applicant's amendment thereto and applicants arguments.

### **New Grounds of Rejection**

#### **35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al (EP 0415794A1 Date September 6, 1991), Senyk et al (Medical Microbiology Immunology Vol. 168 pgs. 91-101 1980), and Hymas et al (US Patent Application No. 20020150593 US Publication Date October 17, 2002).

Mackenzie et al teach an immunogenic composition comprising whole cells from *Mycoplasma cynos* (*M. cynos.*) (see claims 1-2 and pg. 2 lines 40-50 pg. 3 lines 51-55) and a pharmaceutically acceptable carrier administered to animals such as a dog (see abstract, pg. 2 lines 34-54, pg. 3 lines 15-17, pg. 4 last paragraph).

Mackenzie et al does not teach an immunogenic composition, wherein the agent comprises inactivated or attenuated *M. cynos*. Mackenzie et al does not teach an immunogenic composition further comprising an agent selected from the group consisting of: an agent capable of raising an immune response against *Streptococcus equi* sub species *zooepidemicus* (*S. zooepidemicus*) or *Chlamydia* species in a dog, wherein the agent capable of raising an immune response against *S. zooepidemicus* or *Chlamydia* species in a dog comprises an inactivated or attenuated *S. zooepidemicus* or *Chlamydia* species as *Chlamydia abortus*, *Chlamydia felis*, *Chlamydia muridarum*, *Chlamydia pecorum*, *Chlamydia pneumoniae*, *Chlamydia suis* or *Chlamydia trachomatis*.

Senyk et al teach an immunogenic composition comprising betaprone-inactivated chlamydiae from strain LB-1 of *Chlamydia trachomatis* in complete Freund adjuvant to induce animals (see abstract and pg. 2 "Materials and Methods").

Hymas et al teach an immunogenic composition comprising whole cell, inactivated bacterin from *Mycoplasma* specie (see paragraph [0012]) (see paragraphs [0028], column 5, [0045], and [0011]). Hymas et al teach combination of vaccines used to provide immunity against viral or bacterial infections comprising attenuated organisms or inactivated whole organisms in order to present antigens to the recipient's immune system sufficient to produce a protective immune response without giving the recipient the disease (see paragraph [0008]).

It would have been prima facie obvious at the time the invention was made to inactivate the whole cell *Mycoplasma* compositions of Mackenzie et al. in the manner taught by Hymas et al in order to take advantage of the increased safety associated with the use of an inactivated pathogen.

Furthermore given that cited antigens comprising the immunogenic compositions are well known in the art leading to predictable results, it would be obvious to use cited antigens in an immunogenic composition disclosed in Mackenzie et al, Hymas et al, and Senyk et al to create a combination vaccine with cited antigens, thus, it remains obvious to combine them (cited antigens and combination immunogenic compositions), even without an express statement of motivation. KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding an obviousness. See the recent Board Decision Ex parte Smith, -- USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at (<http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

According to MPEP 2144.06, "It is prima facie obvious to combine each immunogenic composition of which is taught by the prior art to be useful for the same purpose, in order to form a immunogenic combination of antigens to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to use *Mycoplasma* immunogenic compositions disclosed by Mackenzie et al and Hymas et al, among the *Chlamydia trachomatis* immunogenic compositions disclosed by Senyk et al because these immunogenic compositions are taught to be useful for that purpose.

5. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al (EP 0415794A1 Date September 6, 1991), Jacobs et al (US Patent No. 6,682,745 Date January 27, 2004 US Filing Date January 27, 2000), and Hymas et al (US Patent Application No. 20020150593 US Publication Date October 17, 2002).

Mackenzie et al teach an immunogenic composition comprising whole cells from *Mycoplasma cynos* (*M. cynos.*) (see claims 1-2 and pg. 2 lines 40-50 pg. 3 lines 51-55) and a pharmaceutically acceptable carrier administered to animals such as a dog (see abstract, pg. 2 lines 34-54, pg. 3 lines 15-17, pg. 4 last paragraph).

Mackenzie et al does not teach an immunogenic composition, wherein the agent comprises inactivated or attenuated *M. cynos*. Mackenzie et al does not teach an immunogenic composition further comprising an agent selected from the group consisting of: an agent capable of raising an immune response against *Streptococcus equi* sub species *zooepidemicus* (*S. zooepidemicus*) or *Chlamydomphila* species in a dog, wherein the agent capable of raising an immune response against *S. zooepidemicus* or *Chlamydomphila* species in a dog comprises an inactivated or attenuated *S. zooepidemicus* or *Chlamydomphila* species as *Chlamydomphila abortus*, *Chlamydomphila felis*, *Chlamydia muridarum*, *Chlamydia pecorum*, *Chlamydia pneumoniae*, *Chlamydia suis* or *Chlamydia trachomatis*.

Jacobs et al teach an immunogenic composition comprising live attenuated bacteria from *S. zooepidemicus*, which are pathogenic for dogs (see column 4 lines 30-40).

Hymas et al teach an immunogenic composition comprising whole cell, inactivated bacterin from *Mycoplasma* specie (see paragraph [0012]) (see paragraphs [0028], column 5, [0045], and [0011]). Hymas et al teach combination of vaccines used to provide immunity against viral or bacterial infections comprising attenuated organisms or inactivated whole organisms in order to present antigens to the recipient's immune system sufficient to produce a protective immune response without giving the recipient the disease (see paragraph [0008]).

It would have been *prima facie* obvious at the time the invention was made to inactivate the whole cell *Mycoplasma* compositions of Mackenzie et al. in the manner taught by Hymas et al in order to take advantage of the increased safety associated with the use of an inactivated pathogen.

Furthermore given that cited antigens comprising the immunogenic compositions are well known in the art leading to predictable results, it would be obvious to use cited antigens in an immunogenic composition disclosed in Mackenzie et al, Hymas et al, and Jacobs et al to create a combination vaccine with cited antigens, thus, it remains obvious to combine them (cited antigens and combination immunogenic compositions), even without an express statement of motivation. KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding an obviousness. See the recent Board Decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at (<http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

According to MPEP 2144.06, "It is prima facie obvious to combine each immunogenic composition of which is taught by the prior art to be useful for the same purpose, in order to form a immunogenic combination of antigens to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to use Mycoplasma immunogenic compositions disclosed by Mackenzie et al and Hymas et al, among the S. zooepidemicus immunogenic compositions disclosed by Jacobs et al because these immunogenic compositions are taught to be useful for that purpose.

6. Claims 1, 8-9, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al (EP 0415794A1 Date September 6, 1991), Senyk et al (Medical Microbiology Immunology Vol. 168 pgs. 91-101 1980), Hymas et al (US Patent Application No. 20020150593 US Publication Date October 17, 2002), and (Hansen et al US Patent No. 5,665,363 Date September 9, 1997).

Mackenzie et al teach an immunogenic composition comprising whole cells from Mycoplasma cynos (M. cynos.) (see claims 1-2 and pg. 2 lines 40-50 pg. 3 lines 51-55) and a pharmaceutically acceptable carrier administered to animals such as a dog (see abstract, pg. 2 lines 34-54, pg. 3 lines 15-17, pg. 4 last paragraph).

Mackenzie et al does not teach an immunogenic composition, wherein the agent comprises inactivated or attenuated M. cynos. Mackenzie et al does not teach an immunogenic composition further comprising an agent selected from the group consisting of: an agent capable

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of raising an immune response against *Streptococcus equi* sub species *zooepidemicus* (*S. zooepidemicus*) or *Chlamydia* species in a dog, wherein the agent capable of raising an immune response against *S. zooepidemicus* or *Chlamydia* species in a dog comprises an inactivated or attenuated *S. zooepidemicus* or *Chlamydia* species as *Chlamydia abortus*, *Chlamydia felis*, *Chlamydia muridarum*, *Chlamydia pecorum*, *Chlamydia pneumoniae*, *Chlamydia suis* or *Chlamydia trachomatis*. Furthermore, Mackenzie et al does not teach an immunogenic composition, further comprising any one or more of: an agent capable of raising an immune response in a dog against (CRCV), wherein said CRCV is a Group II coronavirus; an agent capable of raising an immune response in a dog against (CPIV); an agent capable of raising an immune response in a dog against (CAV-2); an agent capable of raising an immune response in a dog against (CHV); an agent capable of raising an immune response in a dog against *B. bronchiseptica*. Furthermore, Mackenzie et al does not teach an immunogenic composition, wherein the agent capable of raising an immune response in a dog against CPIV comprises inactivated or attenuated CPIV, wherein the agent capable of raising an immune response in a dog against *B. bronchiseptica* comprises inactivated or attenuated *B. bronchiseptica*.

Senyk et al teach an immunogenic composition comprising betaprone-inactivated chlamydiae from strain LB-1 of *Chlamydia trachomatis* in complete Freund adjuvant to induce animals (see abstract and pg. 2 “Materials and Methods”).

Hansen et al teach a biologically active pellet containing a biologically active material and administering subcutaneously into animal such as dogs biologically active pellets in an effective immune stimulating amount (see abstract and column 10 lines 1-10). Hansen et al teach a biologically active material is any material which stimulates an immune response in the animal and will cause the formation of antibodies or induce other resistance mechanisms by the animal (see column 3 lines 30-40). Hansen et al teach viruses (live or killed), attenuated viruses, bacteria (live or killed), detoxified toxins are all well known biologically active materials and particularly useful ingredients in vaccines, bacterins (i.e. bacterin-toxoids are a suspension of killed bacteria along with toxoids) used to protect animals against specific diseases (see column 3 lines 30-67). Hansen et al teach biologically active materials are *Mycoplasma* sp. *Bordetella bronchiseptica*, canine parvovirus, canine adenovirus, canine distemper, canine parainfluenza, and *Chlamydia psittaci* (see column lines 60-67, column 4 lines 1-20). Therefore the biological active materials



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of Hansen et al correlate to: a) an agent capable of raising an immune response against a Chlamydomonada comprising an inactivated Chlamydomonada species in a dog; b) an agent capable of raising an immune response in a dog against an inactivated CPIV, an agent capable of raising an immune response in a dog against an inactivated B. bronchiseptica. Hansen et al teach pharmaceutical pellets prepared with a liquid suspension containing bacterial cells (i.e. bacterial culture fluids) (see column 4 lines 50-60 and Example 2) in a composition comprising an immunogenic composition and adsorbed on aluminum hydroxide gel thus in a pharmaceutically acceptable carrier (see example 2 and column 4 lines 1-25).

Hymas et al teach an immunogenic composition comprising whole cell, inactivated bacterin from Mycoplasma specie (see paragraph [0012]) (see paragraphs [0028], column 5, [0045], and [0011]). Hymas et al teach combination of vaccines used to provide immunity against viral or bacterial infections comprising attenuated organisms or inactivated whole organisms in order to present antigens to the recipient's immune system sufficient to produce a protective immune response without giving the recipient the disease (see paragraph [0008]).

It would have been prima facie obvious at the time the invention was made to inactivate the whole cell Mycoplasma compositions of Mackenzie et al. in the manner taught by Hymas et al in order to take advantage of the increased safety associated with the use of an inactivated pathogen.

Furthermore given that cited antigens comprising the immunogenic compositions are well known in the art leading to predictable results, it would be obvious to use cited antigens in an immunogenic composition disclosed in Mackenzie et al, Hymas et al, Senyk et al, and Hansen et al to create a combination vaccine with cited antigens, thus, it remains obvious to combine them (cited antigens and combination immunogenic compositions), even without an express statement of motivation. KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding an obviousness. See the recent Board Decision Ex parte Smith, -- USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at (<http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

According to MPEP 2144.06, "It is prima facie obvious to combine each immunogenic composition of which is taught by the prior art to be useful for the same purpose, in order to form a immunogenic combination of antigens to be used for the very same purpose ....[T]he idea of

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combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to use Mycoplasma immunogenic compositions disclosed by Mackenzie et al and Hymas et al, among the Chlamydia trachomatis immunogenic compositions disclosed by Senyk et al, and among the Bordetella bronchiseptica immunogenic compositions disclosed by Hansen et al because these immunogenic compositions are taught to be useful for that purpose.

7. Claims 1, 8-9, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al (EP 0415794A1 Date September 6, 1991), Jacobs et al (US Patent No. 6,682,745 Date January 27, 2004 US Filing Date January 27, 2000), Hymas et al (US Patent Application No. 20020150593 US Publication Date October 17, 2002), and (Hansen et al US Patent No. 5,665,363 Date September 9, 1997).

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bronchiseptica. Furthermore, Mackenzie et al does not teach an immunogenic composition, wherein the agent capable of raising an immune response in a dog against CPIV comprises inactivated or attenuated CPIV, wherein the agent capable of raising an immune response in a dog against B. bronchiseptica comprises inactivated or attenuated B. bronchiseptica.

Jacobs et al teach an immunogenic composition comprising live attenuated bacteria from S. zooepidemicus, which are pathogenic for dogs (see column 4 lines 30-40).

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organisms in order to present antigens to the recipient's immune system sufficient to produce a protective immune response without giving the recipient the disease (see paragraph [0008]).

It would have been prima facie obvious at the time the invention was made to inactivate the whole cell Mycoplasma compositions of Mackenzie et al. in the manner taught by Hymas et al in order to take advantage of the increased safety associated with the use of an inactivated pathogen.

Furthermore given that cited antigens comprising the immunogenic compositions are well known in the art leading to predictable results, it would be obvious to use cited antigens in an immunogenic composition disclosed in Mackenzie et al, Hymas et al, Jacobs et al, and Hansen et al to create a combination vaccine with cited antigens, thus, it remains obvious to combine them (cited antigens and combination immunogenic compositions), even without an express statement of motivation. KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding an obviousness. See the recent Board Decision Ex parte Smith, -- USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at (<http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

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8. Claims 1, 8-10, 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al (EP 0415794A1 Date September 6, 1991), Senyk et al (Medical Microbiology Immunology Vol. 168 pgs. 91-101 1980), Hymas et al (US Patent Application No. 20020150593 US Publication Date October 17, 2002), and Acree et al (US Patent No. 4,824,785 Date January 28, 1986).

Mackenzie et al teach an immunogenic composition comprising whole cells from *Mycoplasma cynos* (*M. cynos.*) (see claims 1-2 and pg. 2 lines 40-50 pg. 3 lines 51-55) and a pharmaceutically acceptable carrier administered to animals such as a dog (see abstract, pg. 2 lines 34-54, pg. 3 lines 15-17, pg. 4 last paragraph).

Mackenzie et al does not teach an immunogenic composition, wherein the agent comprises inactivated or attenuated *M. cynos*, or a structural protein of *M. cynos* or a nucleic acid encoding said structural protein, and further comprising an agent selected from the group consisting of: an agent capable of raising an immune response against *Streptococcus equi* sub species *zooepidemicus* (*S. zooepidemicus*) or *Chlamydomphila* species aforementioned above in a dog, wherein the agent capable of raising an immune response against *S. zooepidemicus* or *Chlamydomphila* species aforementioned above in a dog comprises inactivated or attenuated *S. zooepidemicus* or *Chlamydomphila* species aforementioned above, or a structural protein of *S. zooepidemicus* or *Chlamydomphila* species aforementioned above in a nucleic acid encoding said structural protein. Furthermore, Mackenzie et al does not teach an immunogenic composition, further comprising any one or more of: an agent capable of raising an immune response in a dog against (CRCV), wherein said CRCV is a Group II coronavirus; an agent capable of raising an immune response in a dog against (CPIV); an agent capable of raising an immune response in a dog against (CAV-2); an agent capable of raising an immune response in a dog against (CHV); an agent capable of raising an immune response in a dog against *B. bronchiseptica*. Furthermore, Mackenzie et al does not teach an immunogenic composition, wherein the agent capable of raising an immune response in a dog against CPIV comprises inactivated or attenuated CPIV, wherein the agent capable of raising an immune response in a dog against *B. bronchiseptica* comprises inactivated or attenuated *B. bronchiseptica*.

Hansen et al teach a biologically active pellet containing a biologically active material and administering subcutaneously into animal such as dogs biologically active pellets in an effective immune stimulating amount (see abstract and column 10 lines 1-10). Hansen et al teach a biologically active material is any material which stimulates an immune response in the animal and will cause the formation of antibodies or induce other resistance mechanisms by the animal (see column 3 lines 30-40). Hansen et al teach viruses (live or killed), attenuated viruses, bacteria (live or killed), detoxified toxins are all well known biologically active materials and particularly

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useful ingredients in vaccines, bacterins (i.e. bacterin-toxoids are a suspension of killed bacteria along with toxoids) used to protect animals against specific diseases (see column 3 lines 30-67). Hansen et al teach biologically active materials are *Mycoplasma* sp. *Bordetella bronchiseptica*, canine parvovirus, canine adenovirus, canine distemper, canine parainfluenza, and *Chlamydia psittaci* (see column lines 60-67, column 4 lines 1-20). Therefore the biological active materials of Hansen et al correlate to: a) an agent capable of raising an immune response against a *Chlamydia* comprising an inactivated *Chlamydia* species in a dog; b) an agent capable of raising an immune response in a dog against an inactivated CPIV, an agent capable of raising an immune response in a dog against an inactivated *B. bronchiseptica*. Hansen et al teach pharmaceutical pellets prepared with a liquid suspension containing bacterial cells (i.e. bacterial culture fluids) (see column 4 lines 50-60 and Example 2) in a composition comprising an immunogenic composition and adsorbed on aluminum hydroxide gel thus in a pharmaceutically acceptable carrier (see example 2 and column 4 lines 1-25).

Acree et al teach respiratory symptom of canine coronavirus disease is a slight nasal discharge (see column 2 lines 15-25) and further teach canine coronavirus found in the trachea of dogs after administering canine coronavirus intranasally (see example 2) which necessarily teach canine respiratory coronavirus (CRCV) as evidence to the contrary. Acree et al teach an immunogenic composition comprising an attenuated modified live canine coronavirus (see column 3 lines 20-67) to produce an immunological response in dogs (see column 5 lines 20-30). Acree et al teach any combination or singularly of additional attenuated modified live viruses or killed viruses such as Canine Parainfluenza virus, Canine Adenovirus II, and Canine Herpesvirus (see column 4 lines 1-15).

Hymas et al teach an immunogenic composition comprising whole cell, inactivated bacterin from *Mycoplasma* specie (see paragraph [0012]) (see paragraphs [0028], column 5, [0045], and [0011]). Hymas et al teach combination of vaccines used to provide immunity against viral or bacterial infections comprising attenuated organisms or inactivated whole organisms in order to present antigens to the recipient's immune system sufficient to produce a protective immune response without giving the recipient the disease (see paragraph [0008]).

It would have been *prima facie* obvious at the time the invention was made to inactivate the whole cell *Mycoplasma* compositions of Mackenzie et al. in the manner taught by Hymas et

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al in order to take advantage of the increased safety associated with the use of an inactivated pathogen.

Furthermore given that cited antigens comprising the immunogenic compositions are well known in the art leading to predictable results, it would be obvious to use cited antigens in an immunogenic composition disclosed in Mackenzie et al, Hymas et al, Senyk et al, Hansen et al, and Acree et al to create a combination vaccine with cited antigens, thus, it remains obvious to combine them (cited antigens and combination immunogenic compositions), even without an express statement of motivation. KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding an obviousness. See the recent Board Decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

According to MPEP 2144.06, "It is prima facie obvious to combine each immunogenic composition of which is taught by the prior art to be useful for the same purpose, in order to form a immunogenic combination of antigens to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to use Mycoplasma immunogenic compositions disclosed by Mackenzie et al and Hymas et al, among the Chlamydia trachomatis immunogenic compositions disclosed by Senyk et al, among the Bordetella bronchiseptica immunogenic compositions disclosed by Hansen et al, and among the Group II coronavirus (CRCV), Canine Adenovirus II, and Canine Herpesvirus immunogenic compositions disclosed by Acree et al because these immunogenic compositions are taught to be useful for that purpose.

9. Claims 1, 8-10, 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al (EP 0415794A1 Date September 6, 1991), Jacobs et al (US Patent No. 6,682,745 Date January 27, 2004 US Filing Date January 27, 2000), Hansen et al (US Patent No. 5,665,363 Date September 9, 1997), Hymas et al (US Application No. 20020150593 US Publication Date October 17, 2002), and Acree et al (US Patent No. 4,824,785 Date January 28, 1986).

Mackenzie et al teach an immunogenic composition comprising whole cells from *Mycoplasma cynos* (*M. cynos.*) (see claims 1-2 and pg. 2 lines 40-50 pg. 3 lines 51-55) and a pharmaceutically acceptable carrier administered to animals such as a dog (see abstract, pg. 2 lines 34-54, pg. 3 lines 15-17, pg. 4 last paragraph).

Mackenzie et al does not teach an immunogenic composition, wherein the agent comprises inactivated or attenuated *M. cynos*, or a structural protein of *M. cynos* or a nucleic acid encoding said structural protein, and further comprising an agent selected from the group consisting of: an agent capable of raising an immune response against *Streptococcus equi* sub species *zooepidemicus* (*S. zooepidemicus*) or *Chlamydomphila* species aforementioned above in a dog, wherein the agent capable of raising an immune response against *S. zooepidemicus* or *Chlamydomphila* species aforementioned above in a dog comprises inactivated or attenuated *S. zooepidemicus* or *Chlamydomphila* species aforementioned above, or a structural protein of *S. zooepidemicus* or *Chlamydomphila* species aforementioned above in a nucleic acid encoding said structural protein. Furthermore, Mackenzie et al does not teach an immunogenic composition, further comprising any one or more of: an agent capable of raising an immune response in a dog against (CRCV), wherein said CRCV is a Group II coronavirus; an agent capable of raising an immune response in a dog against (CPIV); an agent capable of raising an immune response in a dog against (CAV-2); an agent capable of raising an immune response in a dog against (CHV); an agent capable of raising an immune response in a dog against *B. bronchiseptica*. Furthermore, Mackenzie et al does not teach an immunogenic composition, wherein the agent capable of raising an immune response in a dog against CPIV comprises inactivated or attenuated CPIV, wherein the agent capable of raising an immune response in a dog against *B. bronchiseptica* comprises inactivated or attenuated *B. bronchiseptica*.

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It would have been prima facie obvious at the time the invention was made to inactivate the whole cell Mycoplasma compositions of Mackenzie et al. in the manner taught by Hymas et al in order to take advantage of the increased safety associated with the use of an inactivated pathogen.

Furthermore given that cited antigens comprising the immunogenic compositions are well known in the art leading to predictable results, it would be obvious to use cited antigens in an immunogenic composition disclosed in Mackenzie et al, Hymas et al, Jacobs et al, Hansen et al, and Acree et al to create a combination vaccine with cited antigens, thus, it remains obvious to combine them (cited antigens and combination immunogenic compositions), even without an express statement of motivation. KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding an obviousness. See the recent Board Decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at (<http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

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10. Claims 1, 8-9, 11-12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al (EP 0415794A1 Date September 6, 1991), Senyk et al (Medical Microbiology Immunology Vol. 168 pgs. 91-101 1980), Hymas et al (US Patent Application No.

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20020150593 US Publication Date October 17, 2002), and Brown et al (US Patent No. 5,661,006 Date August 26, 1997).

Mackenzie et al teach an immunogenic composition comprising whole cells from *Mycoplasma cynos* (*M. cynos.*) (see claims 1-2 and pg. 2 lines 40-50 pg. 3 lines 51-55) and a pharmaceutically acceptable carrier administered to animals such as a dog (see abstract, pg. 2 lines 34-54, pg. 3 lines 15-17, pg. 4 last paragraph).

Mackenzie et al does not teach an immunogenic composition, wherein the agent comprises inactivated or attenuated *M. cynos*, or a structural protein of *M. cynos* or a nucleic acid encoding said structural protein, and further comprising an agent selected from the group consisting of: an agent capable of raising an immune response against *Streptococcus equi* sub species *zooepidemicus* (*S. zooepidemicus*) or *Chlamydomydia* species aforementioned above in a dog, wherein the agent capable of raising an immune response against *S. zooepidemicus* or *Chlamydomydia* species aforementioned above in a dog comprises inactivated or attenuated *S. zooepidemicus* or *Chlamydomydia* species aforementioned above, or a structural protein of *S. zooepidemicus* or *Chlamydomydia* species aforementioned above in a nucleic acid encoding said structural protein. Furthermore, Mackenzie et al does not teach an immunogenic composition, further comprising any one or more of: an agent capable of raising an immune response in a dog against (CRCV), wherein said CRCV is a Group II coronavirus; an agent capable of raising an immune response in a dog against (CPIV); an agent capable of raising an immune response in a dog against (CAV-2); an agent capable of raising an immune response in a dog against (CHV); an agent capable of raising an immune response in a dog against *B. bronchiseptica*. Furthermore, Mackenzie et al does not teach an immunogenic composition, wherein the agent capable of raising an immune response in a dog against CPIV comprises inactivated or attenuated CPIV, wherein the agent capable of raising an immune response in a dog against *B. bronchiseptica* comprises inactivated or attenuated *B. bronchiseptica*, wherein the agent capable of raising an immune response in a dog against CRCV comprises a Spike protein or a hemagglutinin-esterase (HE) protein of CRCV, or an immunogenic portion of the Spike or HE protein.

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organisms in order to present antigens to the recipient's immune system sufficient to produce a protective immune response without giving the recipient the disease (see paragraph [0008]).

It would have been prima facie obvious at the time the invention was made to inactivate the whole cell Mycoplasma compositions of Mackenzie et al. in the manner taught by Hymas et al in order to take advantage of the increased safety associated with the use of an inactivated pathogen.

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### Conclusion

12. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner acting supervisor, Patricia Duffy can be reached on 571-272-0855. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie

Examiner

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/Robert A. Zeman/

Primary Examiner, Art Unit 1645